January 20, 2023

Jumin Oh,
Regulatory Affairs Specialist, Global Regulatory Affairs Team
Celltrion USA, Inc.
One Evertrust Plaza, Suite 1207
Jersey City, NJ 07302

Re: EUA210190/S016
Trade/Device Name: Celltrion DiaTrust COVID-19 Ag Rapid Test
Dated: November 10, 2022
Received: November 10, 2022

Dear Jumin Oh:

This is to notify you that your request to update the authorized labeling of the Celltrion DiaTrust COVID-19 Ag Rapid Test; (1) in response to Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022 to revise the authorized use(s) as required and described in Appendix A, and make various updates to the authorized labeling as required and described in Appendix B of the letter, and (2) include with results of additional reactivity studies, is granted. Upon review, we concur that the information submitted in EUA210190/S016 supports the requested updates for use with the Celltrion DiaTrust COVID-19 Ag Rapid Test and fulfills Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022. The Fact Sheet for Healthcare Professionals and Fact Sheet for Patients have been updated by FDA consistent with this revision and are included along with this letter.

By submitting this supplemental request for review by the Food and Drug Administration (FDA), you have complied with and fulfilled Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022, and complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the Celltrion DiaTrust COVID-19 Ag Rapid Test re-issued on May 16, 2022.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health